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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,684	03/20/2000	MICHAEL ANTHONY CAWTHORNE	00537/161002	7046

7590 11/16/2004
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BOSTON, MA 02110

EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/423,684	Applicant(s) CAWTHORNE ET AL.	
	Examiner Hope A. Robinson	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,6,8,10,11 and 32 is/are rejected.
- 7) ☒ Claim(s) 2,3,5,7,9 and 12-31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's response to the Office Action mailed February 25, 2004 on August 25, 2004, is acknowledged.

2. Claims 33-37 have been canceled. Claims 12-23 have been amended. Claims 1-32 are pending and are under examination.

Restriction Requirement

3. Applicant's comments regarding the restriction requirement on page 11 of the response is noted, however, the restriction has been made final and applicant's comments have already been addressed.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. The following grounds of objection/rejection are or remain applicable:

Claim Objection

6. Claims 2-10 and 12-32 are objected to because of the following informalities:

For clarity and precision of the claim language, claims 2-10 and 12-32 should be amended to recite "The" instead of "A". For example, "The method of claim 1", instead of "A method of claim 1" (see claim 2).

Claims 2-3, 5, 7, 9 and 12-31 are objected to as the claims depend from a rejected based claim.

Correction is required.

Claim Rejections - 35 U.S.C. § 103

7. Claims 1, 4, 6, 8, 10-11 and 32 remain rejected under 35 U.S.C. 103(a) for the reasons of record.

Response to Applicant's Arguments:

Applicants argue that hyperamylinemia is only one of the metabolite alterations in obesity and although Huang suggest that it could act as a causative mechanism, there is no indication that it is the only factor or even a primary factor responsible for inducing an obese state. It is further stated that while it is readily admitted that Dunmore does teach that, by preventing hyperamylinemia, somatostatin agonists can be used to treat non-insulin dependent diabetes, however, it would, by no means, be apparent to a skilled artisan that a treatment suitable for type II diabetes would also be generally useful in treating obesity.

Applicant's comments on pages 15-18 have been considered but are not persuasive. The requirement for 35 U.S.C. 103 is a mere teaching or suggestion, which applicant has admitted is

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present. Dunmore et al. teach that somatostatin type-5 receptor agonists reduce hyperamylinamia and disclose pharmaceutical compositions comprising somatostatin agonists such as H-Cys-Phe-Phe-D-Trp-Lys-Thr-Phe-Cys-NH₂ as claimed. Dunmore et al. disclose the presence of an abnormally high concentration of amylin in the blood, for example hyperamylinemia, was found in obese patients and Huang et al. teach that "hyperamylinamia is not simply a passive partner to hyperinsulinemia, but rather it can act as a causative mechanism of insulin resistance and associated metabolic derangements including obesity. Therefore, it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention as a whole because Dunmore et al. disclose that somatostatin type-5 receptor agonists reduce hyperamylinamia found in obese patients and Huang et al. teach that hyperamylinamia plays a causative role in producing obesity, thus one of skill in the art would be motivated to use somatostatin type-5 receptor agonist in the treatment of obesity. Thus, the rejection remains.

Conclusion

8. No claims are presently allowable.

9. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS

[Handwritten signature]
11/4/04

Patent Examiner

[Handwritten signature: Karen Cochrane Carlson]
KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER